URGENT MEDICAL DEVICE RECALL
for Monoject™ Prefill Flush Syringes

August 16, 2013

Attention: Risk Management Director and Materials Management
Please forward this communication to all potential users of the product which may include:

- Director of Nursing
- Director of Pharmacy
- Director of Laboratory Services
- Director of Materials Management
- Director of Infection Control
- Director of Risk Management
- Director of Clinical Affairs
- Clinical Nurse Manager
- Infusion Nurse Manager

Dear Valued Customer,

This letter is to advise you that Covidien is voluntarily recalling specific lots of Monoject™ Prefill Flush Syringes.

**Reasons for Recall:** This recall is being conducted due to the risk that a number of the syringes were filled with water but not subjected to the autoclave sterilization process. These products are labeled as either sodium chloride flush or heparin lock flush. Some of these syringes have the mismatched syringe tip cap, syringe label, filled volume and wrapper. However, for the sodium chloride flush syringes with matched tip cap, syringe label, filled volume and wrapper, there are no visual cues for clinician to identify the problematic products.

**Risk to Health:** If non-sterile fluid is administered there is health risk of life-threatening infection to the blood stream or other areas. Also if the clinician uses the Heparin Lock Flush syringe containing only water on peripheral or venous catheters, the patency of the intravascular device may not be maintained and clotting may occur. This could result in non-functional intravenous access requiring the device to be replaced.

The affected product was produced during January through April of 2013. Our records indicate that you may have received some of the affected product. We are unaware of any adverse events associated with the affected product; however, Covidien is requesting that customers quarantine and return any remaining stock of the lots listed below.

**THIS RECALL APPLIES ONLY TO PRODUCT ID AND LOT NUMBERS LISTED BELOW.** No other lots or product codes of Covidien products are affected by this recall.

<table>
<thead>
<tr>
<th>Product ID</th>
<th>Description</th>
<th>Lot #</th>
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<tbody>
<tr>
<td>8881570121</td>
<td>Monoject™ 0.9% Sodium Chloride Flush Syringe, 12 mL Syringe with 10 mL Fill</td>
<td>13A0084N 13A0094 13B0364 13C0504 13C0514</td>
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<tr>
<td>8881570123</td>
<td>Monoject™ 0.9% Sodium Chloride Flush Syringe, 12 mL Syringe with 3 mL Fill</td>
<td>13A0084N</td>
</tr>
<tr>
<td>8881570125</td>
<td>Monoject™ 0.9% Sodium Chloride Flush Syringe, 12 mL Syringe with 5 mL Fill</td>
<td>13A0084N</td>
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<tr>
<td>8881580121</td>
<td>Monoject™ 10 Units/mL Heparin Lock Flush, 12 mL Syringe with 10 mL Fill</td>
<td>13A0084N</td>
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<tr>
<td>8881580123</td>
<td>Monoject™ 10 Units/mL Heparin Lock Flush, 12 mL Syringe with 3 mL Fill</td>
<td>13A0084N</td>
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<tr>
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<tr>
<td>8881590125</td>
<td>Monoject™ 100 Units/mL Heparin Lock Flush, 12 mL Syringe with 5 mL Fill</td>
<td>13A0084N 13D0824N</td>
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REQUIRED ACTIONS:

1. Immediately quarantine and discontinue use of the affected devices.

2. Please return affected product as follows:

   • CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM COVIDIEN
     Please complete the Monoject™ Prefill Flush Syringes Recalled Product Return Form and fax it to (800) 895-6140 or email it to feedback.customerservice@Covidien.com. If you have affected units to return, Customer Service will respond with a Return Goods Authorization (RGA) number as well as shipping documents, which will cover shipment pickup and all freight costs associated with the return. Once the RGA number is received, please enter this number on the Recalled Product Return Form and include the form with your returned product. For questions regarding the RGA / return process, please contact Covidien Customer Service, M-F, 8am – 6:30pm ET at (800) 962-9888, option 1, and then option 2.

   • If you have distributed the affected products, please notify your customers of this letter

   • Ship affected product(s) with the RGA # provided by Customer Service to:
     Covidien Attention: Monoject™ Prefill Flush Syringes 110 Kendall Park Lane, Atlanta, GA 30336

   • CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR
     Please complete the Monoject™ Prefill Flush Syringes Recalled Product Return Form (attached) and contact your Distributor directly. The completed form should be emailed to the following email address: Mansfield.ProductMonitoring@ovidien.com or faxed to (508) 261-8461. All affected product must be returned through the Distributor.

3. Please respond to Covidien using attached form.

   We ask that all customers reply to Covidien WHETHER OR NOT you have affected product at your site. Your response is vital to our monitoring of the effectiveness of this recall. Please complete the Monoject™ Prefill Flush Syringes Recalled Product Return form and return to Covidien via the instructions provided above.

   Thank you for your business and continued support. This action is being taken with the knowledge of the FDA and other regulatory authorities. If you have any questions or concerns, please do not hesitate to contact your Covidien representative or Covidien Customer Service, Monday through Friday, 8am – 6:30pm ET, at (800) 962-9888, option 1, and then option 2.

   Adverse reactions or quality problems experienced with the use of this product should be reported to FDA and Covidien:

   • Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
   (form available to fax or mail), or
   • Call FDA (800) FDA-1088
   • Call Covidien Quality Assurance at (800)-962-9888, option 8, then extension 2500.

   We sincerely apologize for any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,

Jim Welsh
Vice President, Regulatory Affairs
Medical Supplies
RECALLED PRODUCT RETURN FORM
Monoject™ Prefill Flush Syringes

ALL CUSTOMERS PLEASE COMPLETE THIS FORM IN ITS ENTIRETY.

Date: ___________________________ Title: ___________________________

Name of Person Completing this Form: ___________________________

Direct Phone #: ___________________________ Email: ___________________________

Account Name: ___________________________ Covidien Account #: ___________________________

Account Address: ___________________________

City: ___________________________ State: ___________________________ Zip Code: ___________________________

How did the account purchase this product? (Please check)
  Direct from Covidien: ☐  From a Distributor: ☐

Distributor Name: ___________________________

Address: ___________________________

City: ___________________________ State: ___________________________ Zip Code: ___________________________

Return Goods Authorization (RGA) #: ___________________________ (please include once received from Customer Service)
  No Inventory (Please check): ☐

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<tr>
<th>Part Number</th>
<th>Lot Number</th>
<th>Qty</th>
<th>Case or Each?</th>
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I ACKNOWLEDGE RECEIPT OF THE Monoject™ PREFILL FLUSH SYRINGE RECALL NOTIFICATION DATED AUGUST 13, 2013 AND UNDERSTAND THE RECALL INSTRUCTIONS PROVIDED.

(Signature Required)